



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/553,763

10/21/2005

John Thomas Brandt

X16303

3837

25885 7590 08/08/2008

ELI LILLY & COMPANY

PATENT DIVISION

P.O. BOX 6288

INDIANAPOLIS, IN 46206-6288

EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

08/08/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,763	<b>Applicant(s)</b> BRANDT ET AL.	
	<b>Examiner</b> SHIRLEY V. GEMBEH	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The response filed **10/02/07** presents remarks and arguments to the office action mailed **4/30/07**. Applicant's request for reconsideration of the rejection of claims in the last office action has been considered.

Applicant's arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### **Status of Claims**

Claims 1-4 are pending. Claims 5-14 are cancelled. Claims 1, 3 and 4 are amended.

#### ***Withdrawn Claim Rejections - 35 USC § 102***

Claims 1-2 rejected under 35 U.S.C. 102(b) as being anticipated by Asai et al., EP1350511 A1 translated version of WO 02/051412 is withdrawn based on the argument, however a new rejection is made below.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1618

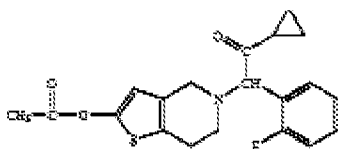
A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Ogletree US 6,509,348 as evidence by Ekelund et al BMC Emergency Medicine, 2001, 2(1) 12 pages).

Ogletree with regard to instant claims 1 and 3, discloses a compound



(known as CS-747) for the treatment of events such as

cardiovascular ischemic, myocardial infarction (acute coronary syndrome is an umbrella term used to cover any group of clinical symptoms compatible with acute myocardial ischemia), after a percutaneous coronary intervention procedure, see col. 3, lines 53-65 and col. 4, lines 39-42. The reference also discloses aspirin maybe used with the claimed compound. See col. 31, lines 31-37 as required by instant claims 2 and 3. See as evidence by Ekelund et al. see section under methods and entire reference to show that the art recognizes these diseases as acute coronary syndrome, see under methods.

**Maintained Claim Rejections - 35 USC § 103**

Claims 1-4 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Asai et al., EP1350511 A1 translated version of WO 02/051412 in view of Mehta et al. The Lancet vol. 358, 2001 p 527-533 (of record).

Applicant argues that, the instant claims are unobvious due to the unexpectedly superior results obtained with the compound of formula I in conjunction with PCI in the TIMI TRITON-38 study. That the TIMI TRITON-38 study compared prasugrel versus clopidogrel (the compound in the Mehta and Smith references) in a study of 13,608 patients with acute coronary syndromes undergoing PCI. Wiviott et al., in Prasugrel versus Clopidogrel in Patients with Acute Coronary Syndromes, N. England J. Med. 357(20) 2001 (2007) concluded that "[I]n patients with acute coronary syndromes with scheduled percutaneous coronary intervention, prasugrel (prasugrel is the non-proprietary name for the compound of formula I) therapy was associated with significantly reduced rates of ischemic events, including stent thrombosis, but with an increased risk of major bleeding, including fatal bleeding" (emphasis added).

In response, in order to overcome the rejection the showing of an unexpected result, the result must be commensurate with the claimed invention.

The instant claims recite a method of treating acute coronary syndrome or high risk vascular diseases by administering compounds of formula I and performing a percutaneous coronary intervention (for claim 1) and further in combination with aspirin (instant claim 3).

In order for the rejection to be overcome by unexpected result, Applicant must compare the invention against the prior art which is relied upon in the rejection and not any prior art, see *Blanchard v Ooms* 68 USPQ 314 91946).

Careful consideration has been given to the remarks and the unexpected result but they are not persuasive for the above reasons. The rejection is maintained as in the last office action dated 12/14/07.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/SVG/  
7/30/08